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Guidance for the Reregistration of Pesticide Products Containing Mecoprop (MCPP) as the Active Ingredient

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Washington, DC

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Washington DC 20460

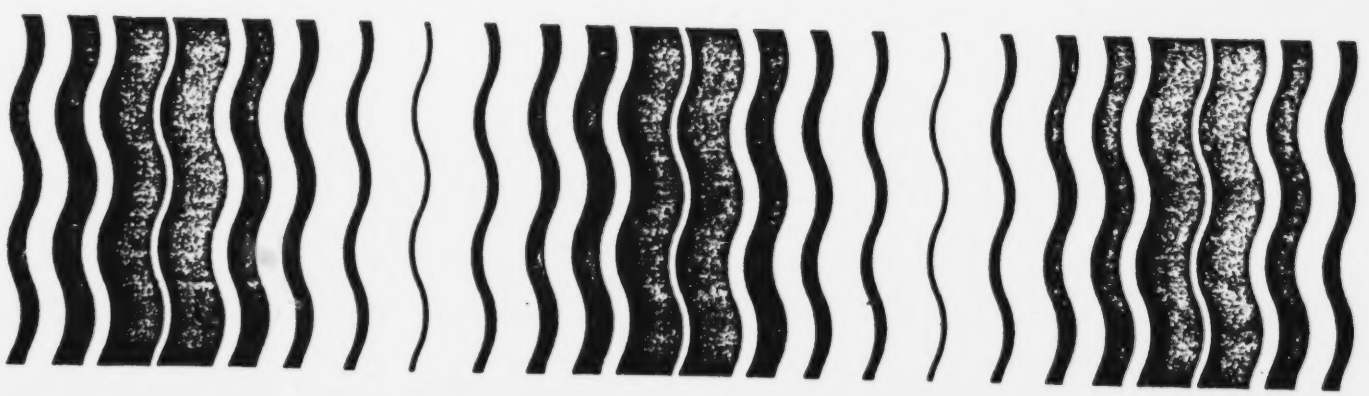
PB89-172746

Pesticides

540/RS-89-030

EPA

Guidance for the Reregistration of Pesticide Products Containing MECOPROP (MCPP) as the Active Ingredient



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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

MECOPROP (MCPP)

AS THE ACTIVE INGREDIENT

CASE NUMBER: 0377

CAS 7085-19-0
CAS 1929-86-8
CAS 1432-14-0
CAS 32351-70-5
CAS 28473-03-2

DECEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGPAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	active ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC_{50}	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
OES	Office of Endangered Species, U.S. Fish and Wildlife Service
ppm	Parts per million

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify

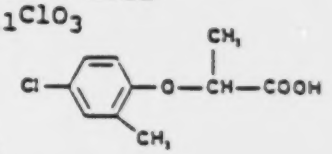
the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

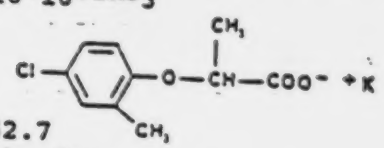
A. Description of Chemicals

The following chemicals are covered by this Registration Standard:

1.

Common name:	MECOPROP; MCPP (preferred name)
Chemical name:	2-(2-methyl-4-chlorophenoxy) propionic acid
Empirical Formula:	$C_{10}H_{11}ClO_3$
Structural Formula:	
Molecular Weight:	214.7
Color:	Colorless to White
Physical State:	Crystalline solid
Melting Point:	94°-95°C
CAS Number:	7085-19-0 (racemate) 93-65-2 (unspecified sterioisomer)
Shaughnessy No.:	031501
Trade names:	MCPP; CMPP; Methoxone; Duplosan KV; RD4593
Other names:	(RS)-2-(4-chloro-o-tolyloxy)-propionic acid; (±)-2-(4-chloro-2-methylphenoxy) propionic acid; (±)-2-(4-chloro-2-methylphenoxy) propanoic acid; (±)-2-[(4-chloro-o-tolyl)oxy]propionic acid; 2-(4-chloro-o-tolyloxy)propionic acid; 2-methyl-4-chlorophenoxy)-propionic acid; 2-(4-chloro-2-methylphenoxy)propionic acid; 2-(4-chloro-o-tolyloxy)propionic acid.

2.

Common name:	MCPP Potassium Salt
Chemical name:	2-(2-methyl-4-chlorophenoxy)-propionic acid, potassium salt.
Empirical Formula:	$C_{10}H_{10}ClKO_3$
Structural Formula:	
Molecular Weight:	252.7
Color:	Data Gap
Physical State:	Data Gap
Melting Point:	Data Gap
CAS Number:	1929-86-8

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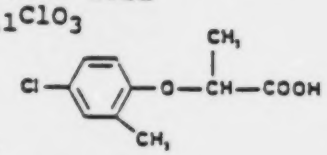
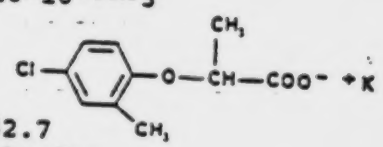
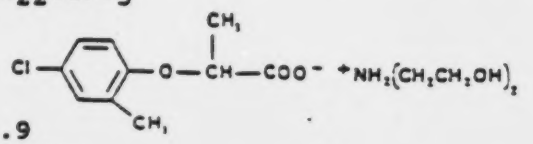
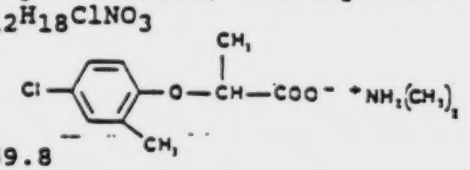
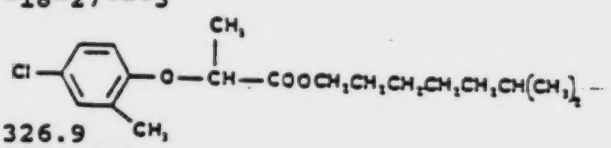
Structural Formula:	
Molecular Weight:	214.7
Color:	Colorless to White
Physical State:	Crystalline solid
Melting Point:	94°-95°C
CAS Number:	7085-19-0 (racemate) 93-65-2 (unspecified sterioisomer)
Shaughnessy No.:	031501
Trade names:	MCPP; CMPP; Methoxone; Duplosan KV; RD4593
Other names:	(RS)-2-(4-chloro-o-tolyloxy)-propionic acid; (±)-2-(4-chloro-2-methylphenoxy) propionic acid; (±)-2-(4-chloro-2-methylphenoxy) propanoic acid; (±)-2-[(4-chloro-o-tolyl)oxy]propionic acid; 2-(4-chloro-o-tolyloxy)propionic acid; 2-methyl-4-chlorophenoxy)-propionic acid; 2-(4-chloro-2-methylphenoxy)propionic acid; 2-(4-chloro-o-tolyloxy)propionic acid.

2.

Common name:	MCPP Potassium Salt
Chemical name:	2-(2-methyl-4-chlorophenoxy)-propionic acid, potassium salt.
Empirical Formula:	$C_{10}H_{10}ClKO_3$
Structural Formula:	
Molecular Weight:	252.7
Color:	Data Gap
Physical State:	Data Gap
Melting Point:	Data Gap
CAS Number:	1929-86-8

	Shaughnessy No:	031503
	Trade names:	Gordon's Mecomec; Hedonal; MCPP; Methoxone M; MCPP-K-4; and Mocopex
3.	Common name:	MCPP Diethanolamine Salt
	Chemical name:	2-(2-methyl-4-chlorophenoxy)-propionic acid,diethanolamine salt
	Empirical Formula:	$C_{14}H_{22}ClNO_5$
	Structural Formula:	
	Molecular Weight:	319.9
	Color:	Data Gap
	Physical State:	Data Gap
	Melting Point:	Data Gap
	CAS Number:	1432-14-0
	Shaughnessy No.:	031516
4.	Common name:	MCPP Dimethylamine Salt
	Chemical name:	2-(2-methyl-4-chlorophenoxy) propionic acid, dimethylamine salt
	Empirical Formula:	$C_{12}H_{18}ClNO_3$
	Structural Formula:	
	Molecular Weight:	259.8
	Color:	Data Gap
	Physical State:	Data Gap
	Melting Point:	Data Gap
	CAS Number:	32351-70-5
	Shaughnessy No.:	031519
5.	Common name:	MCPP Isooctyl Ester
	Chemical name:	2-(2-methyl-4-chlorophenoxy) propionic acid, isooctyl ester
	Empirical Formula:	$C_{18}H_{27}ClO_3$
	Structural Formula:	
	Molecular Weight:	326.9
	Color:	Data Gap
	Physical State:	Data Gap
	Melting Point:	Data Gap
	CAS Number:	28473-03-2
	Shaughnessy No.:	031563
	Trade names:	MCPP, isooctyl ester; Clifton CMPP 60 (butyl and isooctyl esters); and U 46 KV-Ester

B. Regulatory History

The herbicidal properties of MCPP were first reported in the Proceedings of the 3rd British Weed Control Conference in 1956. The first USA federal registration of MCPP was approved in May of 1964. Information on dates of initial registrations are listed below.

Form of MCPP	Date Initially Registered
Potassium Salt	May 1964
Diethanolamine Salt	Feb 1965
Dimethylamine Salt	Sep 1966
Isooctyl Ester	Aug 1971
Acid	Apr 1972

Producers of Technical Pesticide Products:	Aceto Chemical Co., Inc. Akzo Zout Chemie Nederland Dow Chemical USA Gilmore, Inc. A. H. Marks & Co., Ltd Rhone-Poulenc Ag Co.	
Species Controlled:	More than 70 broadleaf weeds	
Registrations: (Active Ingredients in Present Registrations)	Single Active Ingredient Multiple Active Ingredient Total	44 290 334
Special Local Needs Registrations:	MCPP Dimethylamine salt MCPP Diethanolamine salt	6 1

In 1987, the Agency issued a Data Call-In for manufacturing process information to determine if MCPP pesticides become contaminated with chlorinated dibenzo-p-dioxins or dibenzofurans during manufacture. The Agency is concerned that chemicals which contain a halogenated cyclic moiety, such as MCPP, have the potential of becoming contaminated with chlorinated dibenzo-p-dioxins or dibenzofurans under certain conditions of manufacture. Submissions responding to this data call-in were received in early 1988, too late for inclusion in this standard.

C. Use Profile

MCPP products are selective, systemic, post-emergent, broadleaf herbicides that are used primarily on lawns and turf found on golf courses, parks, around homes and institutions, and along roads and fences. They are also used on commercial sod. The approximate percentages of MCPP pesticides used on an annual basis by major use sites are 40 to 64% on golf courses, 32 to 53% on home lawns, 4% on commercial sod, and 1 to 4% for other outdoor applications. Between 1 to 6 million pounds of active ingredients are used annually. Abut 10% of commercial sod is treated with one or more of the MCPP pesticide products; and, this treatment is usually in combination with other herbicides and fertilizers. MCPP is most often combined with the herbicides 2,4-D, dicamba, MSMA, MCPA, and/or DCPA in premixes or tank mixed form. Other MCPP use information is summarized below.

Pests Controlled:	Used especially for control of prostrate chickweed, stitchwort, ground ivy, knowtweed, clover and plantain.
Registered Uses:	<u>Terrestrial nonfood</u> Golf courses, lawns, ornamental and sports turf, and general indoor/outdoor treatments. <u>Aquatic nonfood</u> Drainage ditch banks. <u>Forest trees</u> Site preparation.
Principle Uses:	Ninety-six percent of the production is used on turf, including lawns, sport turf and commercial sod production. A small percentage (1-4%) is used in noncrop areas such as rights-of-way, drainage ditch banks and forest site preparation.
Method of Application:	Foliar applications by ground equipment including spreader, sprayer, and pressurized hose-end sprayer. Application by air on specific noncropland sites.

Rates of Application:	<u>Terrestrial Nonfood Crop</u> 0.05-0.19 lbs ai/5000 sq ft. 0.02-0.6 lbs acid equivalents (ae)/5000 ft. 0.7-0-4.0 lbs ae/A. <u>Aquatic Nonfood Crop</u> 1.07-0.15 lbs ae/5000 ft. <u>Forest Trees</u> 2.0-4.0 lbs ae/A.
Formulations:	Granular, 0.035%-0.84%; wettable powder, 2.5%-15.1%; emulsifiable concentrate, 0.145%-51.9%; soluble concentrate/liquid, 0.91%-51.9%; ready to use, 0.1%-3.28%; pressurized liquid, 0.108%-0.308%.
Mode of Activity:	Disrupts normal cell division by stimulation of mitotic of activity.

III. AGENCY ASSESSMENT

The Agency has reviewed all data in Agency files as of November 21, 1987, supporting the registration of MCPP pesticides. The Agency's scientific findings and conclusions are discussed in this section.

A. Health Effects

Toxicity studies have been submitted on MCPP acid but not on the salts or the isooctyl ester. The studies on MCPP acid are discussed below. The toxicity data set for MCPP acid is complete except for a dermal sensitization study, a 21-day dermal toxicity study and a Chinese Hamster bone marrow cytogenetics study, which are required. Chronic toxicity, oncogenicity, reproduction and general metabolism studies are not required because MCPP and its salts and ester do not have food uses.

The potassium salt is regarded as equivalent to MCPP acid, so a separate toxicity data set is not required. The diethanolamine salt, dimethylamine salt and the isooctyl ester are more complex moieties and may display different toxicological properties. Therefore a full set of acute studies, including inhalation, subchronic (21-day) dermal toxicity, teratogenicity and mutagenicity studies are required for each of these materials.

1. Acute Toxicity

Technical MCPP acid can be lethal following acute oral exposure, but the toxicity is low. Acute oral exposure of rats to 500 mg/kg or greater caused labored breathing, prostration, and death (LD_{50} = 558 mg/kg of technical MCPP--Toxicity Category III).

The dermal toxicity is low. Application of 2 g/kg to skin of rabbits caused no deaths, placing MCPP acid in Toxicity Category IV via this route.

Available data are inadequate to characterize the acute inhalation toxicity of MCPP.

2. Primary Eye Irritation

Sufficient data are available to indicate that technical MCPP acid produces persistent corneal opacities, iritis, and conjunctival irritation in both washed and unwashed eyes. MCPP acid causes significant and persistent eye irritation, which places it in Toxicity Category I.

3. Primary Dermal Irritation

Sufficient data are available to indicate that technical MCPP acid causes no dermal irritation in rabbits exposed for 24 hours to 0.5g on both abraded and unabraded skin.

4. Acute Delayed Neurotoxicity

No data are available on the acute delayed neurotoxicity of MCPP. Since this test is only required for organophosphate inhibitors of cholinesterase or analogs or metabolites of such inhibitors, and MCPP does not fall in one of these categories, a study is not required.

5. Subchronic Oral

An acceptable study in rats is available on the subchronic oral toxicity of technical MCPP acid. Oral exposure of 15 rats/sex to technical MCPP for 90 days at doses of 3, 9, and 27 mg/kg caused increased creatinine levels in females and decreased glucose levels in males at 27 mg/kg; increased kidney weights in both sexes at 27 mg/kg and males at 9mg/kg; and increased relative kidney weights in both sexes at 9 and 27 mg/kg. The NOEL was 3 mg/kg.

6. Subchronic Dermal

Data are not available on the subchronic dermal toxicity of MCPP.

7. Teratogenicity

A teratogenicity study in rats with MCPP acid showed no maternal effects, but, at 125 mg/kg, increased intra-uterine deaths, decreased crown/rump lengths, and an increased incidence of delayed or absent ossification of the sternebrae were reported. Twenty eight female rats/dose were given doses of 20, 50, or 125 mg/kg of MCPP on days 6-15 of gestation. There were 38 control females. The "No Observable Effect Level" (NOEL) was 50 mg/kg.

A teratogenicity study in rabbits showed no fetotoxic or teratogenic effects, and only slight body weight gain differences in the mothers exposed to 75 mg/kg. Fifteen rabbits/dose were given 12, 30, or 75 mg/kg/day of MCPP acid on days 6-18 of gestation. There were 30 control rabbits. There were no effects of exposure on fetotoxicity or teratogenicity measures. The maternal NOEL was 30 mg/kg. The developmental NOEL was greater than 75 mg/kg.

8. Mutagenicity.

a. Gene Mutations. Sufficient data are available to demonstrate the potential of MCPP acid to cause gene mutations. In an acceptable study, no increases were seen in either: (1) Reverse mutation in four Salmonella strains exposed to paper discs impregnated with 2000 ug MCPP (spot test), in both the presence and absence of liver microsomes from rats treated with phenobarbital; or (2) Forward mutation to streptomycin resistance in S. coelicolor A3(2) exposed to increasing concentrations of MCPP up to 1000 ug, in both spot and standard plate incorporation tests, also with and without metabolic activation of rat liver microsomes with phenobarbitol.

b. Chromosomal aberration. Available data are inadequate to characterize the effects of MCPP on chromosomal aberrations. A Chinese Hamster bone marrow cytogenetics study is required.

c. Other Tests. Sufficient data are available to characterize the effects of MCPP acid on sister chromatid exchange (SCE). MCPP caused an increase in SCE after single oral doses of 470 and 3800 mg/kg in Chinese Hamsters. MCPP was positive for increasing SCEs in a dose-dependent fashion above the control value of 3.06 SCEs/cell, at single oral doses of 470 mg/kg (3.77 SCEs/cell, $p < 0.05$) and 3800mg/kg (5.21 SCEs/cell, $p < 0.01$), both doses also causing clinical toxicity.

10. Special Studies

As discussed below in Section II. B. 2, Applicator Exposure, additional data are needed to assess the risk posed by the teratogenic potential of MCPP. A dermal absorption study is needed to refine exposure assessments. If the dermal absortion study shows there is significant absorption of MCPP, a dermal teratogenicity study will be required.

B. Human Exposure

1. Poisoning Incidents

There are no reports of poisoning incidents for MCPP.

2. Applicator Exposure

a. Preliminary Risk Assessment

One biological monitoring study reported on results of urinary MCPP excretion in commercial lawn applicators. The study measured exposure to applicators applying a mixture of MCPP, 2,4-D, and Dicamba to lawns with hand-held large droplet nozzle sprayers. The concentration of MCPP used in that study was 330 mg/l. There was no MCPP detected in applicators' urine samples greater than 0.01 ppm, the lowest level detectable with the analytical method used.

The Agency used surrogate data to evaluate expected exposure associated with the handling of MCPP. Exposure and risk estimates were made based on the three typical uses of MCPP for mixers, loaders, and applicators using open pour and closed loading for 1) commercial lawn, 2) commercial sod use with compressed air and hose end sprayers, and for 3) home-owner use. The results are discussed below and summarized in the table which follows.

Exposure to an individual mixing, loading and applying MCPP on a commercial sod farm was estimated to be 1.0 mg/kg/day. This estimation assumed that the mixer/loader wore gloves and a long sleeved shirt and long pants during the open pour loading, and then applied the MCPP using ground boom equipment (without wearing gloves). Based on the NOEL of 50 mg/kg/day for developmental effects, and a dermal absorption of 100%, the calculated MOS for the commercial sod farmer is estimated to be 50.

The exposure for the commercial home lawn mixer/loaders using an open pour system is estimated to be about 0.43 mg/kg/day, assuming gloves, a long sleeved shirt, and long pants are worn. This is equivalent to a MOS about 120 for the mixing and loading operation, based on a NOEL of 50 mg/kg/day, a dermal absorption of 100%, and surrogate data from the 1987 Dinoseb testimony of Curt Lunchick. The applicator was assumed to be a different individual than the mixer/loader.

The MOS for the homeowner was calculated assuming short sleeved shirts, long pants and shoes were worn during all handling operations, including application using

compressed air sprayers or hose end sprayers. The typical application was assumed to involve the use of 0.36 lb active equivalent MCPP/acre for 3.7 hours a day. Surrogate data published by J.E. Davis, et al. were used to roughly estimate the exposure to homeowners.

Based on the 50 mg/kg/day NOEL and a dermal absorption of 100%, the exposure to homeowners would be about 0.024 mg/kg/day (MOS=2100) if compressed air sprayers were used, and be about 0.082 mg/kg/day (MOS=610) if hose end sprayers were used. (Exposure estimates may be underestimated because homeowners typically wear only minimal clothing during pesticide treatment.) The Davis study was considered too limited for a final exposure assessment for the reregistration of MCPP.

The Agency believes these estimates overstate the actual risk. Most liquid formulations have dermal absorption of 50% or less (usually 5-25%) and not 100%. The Agency finds that the MOS for commercial sod farmers and workers exposed through other uses would probably be over 100 when corrected for the actual extent of dermal absorption.

TABLE OF MCPP EXPOSURE ESTIMATES AND MARGINS OF SAFETY (MOSs)

USE	EXPOSURE ESTIMATE	MOS ESTIMATE
Commercial Lawn Use		
Mixer/Loader		
Open Pour - long pants, long sleeves, gloves	0.430 mg/kg/d	120
Closed Loading - long pants, long sleeves, gloves	0.007 mg/kg/d	7100
Applicators	No available data	
Homeowner Use		
Compressed Air Sprayer	0.024 mg/kg/d	2100
Hose End Sprayer	0.082 mg/kg/d	610
Commercial Sod Farm Use		
Mixer/Loader		
Open Pour - long pants, long sleeves, gloves	0.780 mg/kg/d	64
Closed Loading - long pants, long sleeves, gloves	0.012 mg/kg/d	4200
Applicators		
Open Pour - no protection	0.220 mg/kg/d	230
Closed Loading - no protection	1.000 mg/kg/d	50
	0.230 mg/kg/d	220

b. Exposure Data Requirements

Applicator Exposure Data

Because of the inadequacy of the available exposure data, the Agency is requiring exposure studies for the following uses: commercial home lawns (hose end sprayer, power sprayer, back pack); commercial turf (ground boom); and homeowner use (hose end sprayer and compressed air sprayer). Exposure studies for any other uses of MCPP should also be included. Protocols for these studies should be submitted for Agency approval prior to initiation of the studies.

Reentry Data

MCPP meets both the toxicity and exposure criteria for requiring reentry data. MCPP has been determined to be a developmental toxicant and workers may receive post-application exposure to MCPP through its commercial use on turf. Thus ,the Agency is requiring foliar dissipation, soil dissipation, and dermal exposure studies. These data are needed to assess exposure to MCPP residues resulting from reentry into treated areas on commercial turf farms to harvest or handle treated turf. Respiratory exposure data requirements are reserved, pending submission and Agency evaluation of the complete toxicology data base for MCPP, including dermal and inhalation toxicity.

These data will also be used to assess the risks to persons exposed to residues on lawns, golf courses and other areas where MCPP is applied.

C. Environmental Fate Profile

Environmental fate studies partially satisfy the data requirements for the MCPP acid and its inorganic potassium salt. Studies were presented on the MCPP acid only. There are no acceptable studies for the organic salt and ester forms of MCPP. The available data are insufficient to fully assess the environmental fate of these MCPP pesticides. Data for terrestrial nonfood and aquatic nonfood uses must be submitted for all each MCPP pesticide (see table A).

1. Hydrolysis

Supplemental hydrolysis data indicate that MCPP acid was stable to hydrolysis: Ring-labeled [^{14}C]MCPP (96.9% pure) at 51-52 ppm did not hydrolyze during 740-751 hours of incubation in sterile buffered aqueous solutions (pH 5, 7, and 9) at 25 C.

2. Photodegration in Water

There was slow photodegradation in water for the same ring labeled [^{14}C]MCPP formulation, with a half-life of 739 hours at the same pHs under continuous irradiation with artificial light. Two major and several minor degradates were isolated. There was no degradation of the MCPP acid formulation in the dark control solutions during 739-748 hours of incubation.

3. Leaching and Adsorption/Desorption of Aged MCPP Residues

Based on batch equilibrium experiments, ring-labeled [^{14}C]MCPP acid (>96% purity) at 0.606-12.0 ug/mL, was very mobile in sand, sandy loam, silt loam, and silty clay loam soils; Freundlich Kads values ranged from 0.199 to 0.687. The equilibrations were conducted in 3 g/10 mL soil:solution for 1 hour. Adsorption was strongly correlated with the organic matter content of the soils (correlation coefficients ranged from 0.950-0.999). In general, 25-51% of MCPP was desorbed from the soils after 1 hour of shaking with MCPP-free solutions.

Based on soil TLC experiments, ring-labeled [^{14}C]MCPP acid (>96.3% purity) was very mobile in sand, sandy loam, and silt loam soils (Rf 0.93-1.0), and was mobile in silty clay loam soil (R_f 0.74).

Based on soil TLC experiments, unaged ring-labeled[^{14}C]MCPP acid (>96.3% purity) was mobile (Rf 0.86) in sandy loam soil. However, supplemental information indicated that uncharacterized aged (30 days) [^{14}C]MCPP residues were immobile in sandy loam soil (R_f 0.08).

4. Ground Water Assessment

Available data indicate that MCPP acid is mobile in many mineral soils, and if not first degraded, may potentially leach to groundwater. However, it is unclear whether it is possible for there to be sufficient persistence in the root zone to allow measurable leaching to ground water. No ground water monitoring studies are required at this time, but if the requested environmental fate studies indicate that MCPP or its degradates remain in water and may leach significantly, a monitoring study may be required.

5. Pesticide Accumulation in Fish

There is low level bioaccumulation of MCPP acid in fish. [^{14}C] MCPP residues accumulated in bluegill sunfish with bioconcentration factors of 1.2, 5.5, and 3.0X in edible tissues, nonedible tissues, (head, gills, viscera, and fins), and whole fish, respectively, during 28 days of exposure at 1 ppm in a flow-through system. Maximum levels of [14C] residues were 1.35 ppm in edible tissues, 5.62 ppm in non-edible tissues, and 3.09 ppm in whole fish. In the edible tissues, MCPP residues were found to be 0.23-0.24 ppm at 21 and 28 days post treatment. The major degradate in the edible tissues was "mecoprop methyl", which was isolated at 0.34 ppm and 0.47 ppm at 21 and 28 days, respectively. At 21 and 28 days posttreatment, two unidentified degradates were 0.05-0.19 ppm; uncharacterized residues in the water soluble phase of the extracts were 0.09-15.4 ppm; and unextractables were 0.24-0.26 ppm. Residues accumulated at 28 days were depurated quickly; at day 14 of depuration, [^{14}C] residues were 0.03 ppm in edible tissues, 0.64 ppm in nonedible tissues, and 0.29 ppm in whole fish. The Agency finds that the observed levels of bioaccumullation are of virtually no significance.

D. Ecological Effects

1. End Use Products

The only studies received which tested MCPP end use products were those in which the test substance a mixture of one or more forms of MCPP and other active ingredients. Because data on mixtures are not acceptable, these studies were not reviewed. End use product testing is incomplete as discussed below and data are required.

2. Technical Products

a. Avian Studies

Avian toxicity data are complete for MCPP acid, partially complete for MCPP dimethylamine salt, and nonexistent for all other MCPP pesticides. However, the Agency will accept data on MCPP acid to support uses of the potassium salt of MCPP. (See data requirements in the Data Table A in Appendix I.)

1) Avian single-dose oral studies on MCPP acid indicate an acute oral LD_{50} value of 700 mg/kg for the bobwhite quail. MCPP acid may therefore be considered slightly toxic to avian species on an acute basis. Based on available toxicity information, no precautionary labeling for MCPP acid nor MCPP potassium salt is indicated. No acute oral studies were submitted for

the salts or ester MCPP products; therefore, no acute toxicity determinations can be made at this time for the diethanolamine salt, dimethyl salt, and the isooctyl ester forms of MCPP.

2) Avian dietary studies on MCPP acid indicate LC_{50} values of >5620 ppm for the mallard and 5000 ppm for the bobwhite. MCPP acid may therefore be considered practically non-toxic to avian species on a subacute basis. Dietary studies for MCPP dimethylamine salt indicate LC_{50} values greater than 12000 ppm for the mallard and 14000 ppm for the Japanese quail. However, the Japanese quail is not considered representative of an upland game bird in the United States. The bobwhite quail is the preferred species. Thus, the Japanese quail study does not fulfill EPA requirements.

Additional avian dietary data are required on the MCPP dimethylamine salt; and, all data are required for the diethanolamine salt and the isooctyl ester. Although Guidelines requirements are only partially fulfilled, the above data indicate that MCPP dimethylamine salt has very low toxicity to avian species on a subacute dietary basis. No determination of dietary toxicity to avian species can be made for the diethanolamine salt or the isooctyl ester because of a lack of acceptable studies.

3) Avian Reproduction Testing. No avian reproduction studies were submitted. There is insufficient toxicity and environmental fate data available at this time to determine if this test is required for any of the forms of MCPP.

b. Aquatic Studies

1) Acute Freshwater Fish Toxicity Testing.

Available freshwater fish toxicity studies indicate that MCPP acid (technical formulation) has very low acute toxicity to freshwater fish (rainbow trout LC_{50} = 124 ppm). The submission of rainbow trout (a coldwater species) studies only partially satisfied the freshwater fish data requirements for the MCPP acid and MCPP potassium salt. The data requirement for testing a warmwater species has not been fulfilled.

A determination of acute toxicity for technical or end-use products to freshwater fish cannot be made for the dimethylamine salt, the diethanolamine salt, or the isooctyl ester because of a lack of toxicity data.

2) Acute Freshwater Aquatic Invertebrate Testing. There were no acceptable acute freshwater aquatic invertebrate data received. Therefore, the requirement for acute toxicity testing for technical and end use products containing MCPP on freshwater aquatic invertebrates has not been fulfilled.

3) Effects on Estuarine and Marine Organisms. Given that MCPP formulations are used in drainage ditch-banks and that MCPP is a major herbicide used on turf (with golf courses in the mid-Atlantic region accounting for most of this use), significant runoff to estuarine/ marine environments may be expected. There were no studies on estuarine and marine organisms submitted for review. Therefore, the requirement for acute toxicity testing for the acid and all salt and ester forms of MCPP on estuarine and marine organisms has not been fulfilled. Testing is required for some formulations and reserved for others, pending the results of acute aquatic freshwater fish and acute aquatic freshwater invertebrate studies and environmental fate data.

4) Fish Early Life-Stage and Aquatic Invertebrate Life-Cycle Testing. There were no fish early life-stage nor aquatic invertebrate life-cycle test results submitted using either technical or typical end use MCPP products. There is insufficient acute toxicity data and environmental fate data available at this time to determine if these tests are required. Thus, requirements for testing technical and end use acid, salt, and ester formulations of MCPP are reserved for fish early life-stage and aquatic invertebrate organisms.

c. Nontarget Plants

There are no acceptable data for toxicity of any MCPP formulation to nontarget plants. Therefore, no assessment of toxicity can be made at this time.

All MCPP formulations are labeled to control a variety of broadleaf weeds. Therefore, Tier I testing will not be required because, by definition, herbicides are hazardous to plants. In order to assess the potential hazard to nontarget plants, the Tier II nontarget plant studies as specified in the data table in Appendix I are required for all forms of MCPP. Further, for those MCPP formulations for which drainage ditchbank application is identified (dimethylamine salt, potassium salt, isooctyl ester), Tier II aquatic plant testing must utilize all of the following species: 1) duck-weed (Lemna gibba), 2) marine diatome (Skeletonema costatum), 3) blue-green alga (Anabaena flos-aquae),

4) freshwater green alga (Selenastrum capricornutum), and 5) a freshwater diatom. For those MCPP formulations not identified as having drainage ditchbank application (MCPP acid and diethanolamine salt), testing may be completed using Selenastrum capricornutum.

d. Endangered Species

There are no data to indicate whether MCPP acid or any MCPP salt or ester formulation may affect endangered plant or animal species. Therefore, the Agency cannot assess the potential of MCPP or its salts or ester to adversely affect endangered species.

e. Nontarget Insects

There are no data to indicate whether products containing MCPP acid or its salts and ester affect honeybees and nontarget insects. No determination can be made that MCPP acid or any salt or ester form of MCPP will adversely affect nontarget insects. No data are required at this time.

E. Other Science Findings

MCPP acid and its salts and ester contain a chlorinated phenoxy group within their structure. The Agency has found that chemicals having such components in their structure may have been produced under conditions which can lead to the formation of chlorinated dibenzo-p-dioxins or dibenzofurans as manufacturing impurities. Accordingly, the Agency has required the submission of manufacturing process information to address this possibility. The Agency will evaluate these data to assess the likelihood of dioxin/furan formation during manufacture. If the manufacturing process data show that chlorinated dibenzo-p-dioxins or dibenzofurans are likely to occur, the Agency may require analytical data to characterize or quantify these contaminants. The Agency's concern about chlorinated dibenzo-p-dioxins and dibenzofurans is based on the extreme toxicity of 2,3,7,8-tetrachloro-dibenzo-p-dioxin, which causes lethal effects in aquatic species, birds and some mammals. These impurities are also known to be carcinogenic, teratogenic, fetotoxic, and acnegenic.

The Agency is also concerned that the amine salts of MCPP may become contaminated by nitrosamines under certain conditions of manufacture and storage. Information on the manufacture and storage of products containing MCPP amine salts is required to assess possible contamination. The Agency's concern is based on the well-established carcinogenicity of nitrosamines.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

The Agency has made the following determinations based on review and evaluation of all available acceptable data on MCPP pesticides.

1. Special Review

The Agency is deferring a decision on initiating a Special Review of MCPP pesticides until data needed to refine worker exposure estimates have been submitted and evaluated.

Rationale: A teratogenicty study in rats showed a NOEL of 50 mg/kg for developmental effects of MCPP acid. The Agency estimated exposures to workers and users of MCPP pesticide products and found that margins of safety were below 100 for mixer/loaders and applicators handling MCPP in commercial sod farms. These estimates are based upon the assumption that the rate of dermal absorption is 100 percent. The Agency is requiring dermal absorption and applicator exposure data so that these risk estimates can be refined. When these data are available, the Agency will evaluate them to determine whether further regulatory action is warranted.

Based on dermal absorption data obtained on other pesticides, the Agency believes that the rate of dermal absorption is likely to be below 50 percent. Therefore, the Agency believes that risks to workers are likely to be acceptable for dermal absorption. Accordingly, other than requiring the use of protective clothing (which would be required in any case), the Agency is not imposing any interim risk reduction measures.

2. Restricted Use

The Agency will not restrict the use of MCPP products at this time.

Rationale: The Agency does not have sufficient information to determine that classification of MCPP pesticides as restricted use pesticides is warranted. The Agency is requiring data needed to refine worker exposure estimates. When these data become available, the Agency will assess the risks posed by use of MCPP pesticides and will reexamine its position on classification.

3. Exposure Data Requirements

The Agency is requiring a dermal penetration study and exposure estimates for applicators involved in commercial lawn uses. A dermal teratology study may also be required if the dermal absorption of MCPP is significant. These data are needed to assess the teratogenic risk posed by MCPP pesticides to persons handling MCPP pesticides for lawns, turf, and sod applications.

Rationale: A preliminary risk assessment of the developmental effects of MCPP, based upon limited exposure data and the assumption of 100% dermal absorption, showed inadequate margins of safety for some categories of workers. The required studies will provide data needed to refine the exposure estimates for these workers and more accurately assess the margins of safety.

4. Basic Data Requirements

The Agency will require data specific to the amines and the ester formulations as well as the acid, as reflected in the data tables.

Rationale: When MCPP is formulated as an ester or amine, the physical characteristics, biological activity and fate in the environment may be affected. The Agency has little or no data to evaluate the effects of the ester or amine derivatives of MCPP. Data on each amine and ester derivative are needed to evaluate the hazards associated with each registered form of MCPP.

5. Ground Water Concerns

The Agency will evaluate the potential of MCPP pesticides to contaminate ground water after receiving and evaluating additional required environmental fate studies. Until these studies are submitted and evaluated, the statement given in section IV. D is required.

Rationale: MCPP pesticides have been identified as chemicals with the potential to contaminate ground water because they are mobile in mineral soils. It is unknown whether MCPP will persist sufficiently in the soil surface to prevent measurable leaching into ground water.

6. Reentry Data Requirement

The Agency will require reentry data for MCPP pesticides. Workers are not to reenter treated areas until the spray has dried or the dust has settled. (See label statements given in Section IV. D.)

Rationale: Reentry data requirements are triggered by the finding that MCPP is teratogenic in the rat and that its uses, such as the commercial sod farm use, require workers to reenter MCPP-treated areas. It is therefore necessary to obtain data needed to estimate the extent of worker exposure to MCPP residues. In order to minimize exposure to MCPP residues, workers should not reenter treated areas unitl the spray has dried or the dust has settled.

7. Protective Clothing Requirement

The Agency is requiring that protective clothing be used. Mixer/loaders and applicators must wear long pants, long sleeved shirts, and gloves. Persons applying liquid MCPP products such as sprays, are required to use goggles to cover their eyes. (See label statements given in Section IV. D.)

Rationale: These measures are needed to reduce dermal and ocular exposure to MCPP. Eye exposure should be reduced because MCPP is extremely irritating to the eye (it has been placed in toxicity category I for primary eye irritation). Exposure via the dermal route, which is the major route of exposure, should be reduced because of the teratogenic potential of MCPP.

8. Endangered Species

Until all required toxicity studies are received and evaluated, there can be no determination that MCPP acid or any MCPP pesticide would affect endangered animal or plant species. Therefore, no endangered species labeling statement is required at this time.

Rationale: The Agency lacks data to show whether the use of MCPP pesticides affect any endangered plant or animal species. Phytotoxicity data on nontarget plants are required. If data indicate that endangered species may be adversely affected by registered uses of MCPP, the Agency will initiate consultation to determine what measures are necessary to preclude jeopardy to those species.

9. Dioxins/Dibenzofurans

The Agency is requiring the submission of manufacturing and product chemistry data to address the potential contamination of MCPP and its salts, amines and esters with chlorinated dibenzo-p-dioxins and dibenzofurans.

Rationale: Chemicals with chlorinated cyclic components may become contaminated with chlorinated dibenzo-p-dioxins and dibenzofurans under certain conditions of manufacture. Information on the manufacture of MCPP acid and its salts and

esters is required to assess whether contamination with such impurities is likely to occur. The Agency's concern is based upon the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin and the potential toxicity of related compounds.

10. Nitrosamines

The Agency is requiring the submission of analytical and product chemistry data to address the possible contamination of MCPP amines with nitrosamines.

Rationale: Nitrosamines might be produced in MCPP amine salts under certain conditions of manufacture and storage. Information on the manufacture and storage of MCPP amine salts is required to assess possible contamination. The Agency's concern is based on the well-established carcinogenicity of nitrosamines.

11. Data for Immediate Agency Review

The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain of the data being required are essential to resolve risk concerns, or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency: product chemistry, environmental fate, dermal absorption, applicator exposure and reentry data, toxicity data on MCPP salts and ester, and Tier II phytotoxicity data.

12. Continuation of Registration.

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing MCPP may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain one or more of the forms of MCPP (Mecoprop), bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain one or more of the following MCPP products: MCPP acid; MCPP potassium salt; MCPP diethanolamine salt; MCPP dimethylamine salt; MCPP isooctyl ester. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing any of the above forms of MCPP pesticides provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products bearing Federally registered uses. The EPA Compendium of Acceptable Uses lists all registered uses, as well as approved maximum application rates and frequencies (for availability, see page 1).

The use patterns currently registered are nonfood terrestrial, aquatic, forestry, and domestic.

D. LABELING

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

Time Frames for Compliance. Pesticide products containing one or more of the forms of MCPP may not be released for shipment by the registrant after December 1989, unless the products bear

amended labels which comply with the requirements of this Standard.

Likewise, pesticide products containing one or more of these forms of MCPP may not be distributed or sold after December 1990, unless the products bear amended labels which comply with the requirements of this Standard.

The following specific information must appear on the labeling of all manufacturing and end use MCPP products:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT
2-(2-methyl-4-chlorophenoxy) propionic acid _____%

OR

(Applicable salt or ester) ..... _____%
2-(2-methyl-4-chlorophenoxy) propionic acid equivalent: ..... _____%

INERT INGREDIENT(S)
_____ ..... _____%

2. Use Pattern Statements

Manufacturing-Use Products
All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns.

End-Use Products
Labeling must specify sites which are listed in the EPA Compendium of Acceptable Uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

"Do not discharge effluent containing this product into lakes streams, ponds, estuaries, oceans, or public waters, unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment

plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Statements for End-Use Products

Ground Water Contamination:
"Although highly mobile, in general phenoxy herbicides such as MCPP are not sufficiently persistent to reach groundwater from use as specified on product labels. Most cases of ground water contamination involving phenoxy herbicides have been associated with mixing/loading and disposal sites. Caution should be exercised when handling MCPP pesticides at such sites to prevent contamination of water supplies."

Protective Clothing:
"Mixers/loaders and applicators must wear long pants, long sleeved shirts and gloves. Persons applying liquid MCPP products such as sprays are required to use goggles to cover their eyes." Mixers/loaders may use face shield or goggles during mixing/loading operations, in addition to the protective clothing.

Worker Reentry:
"Do not reenter or permit workers to reenter treated areas until sprays have dried or dusts have settled."

Nontarget Plant Species:
Aquatic Uses
"Drift or run-off may adversely affect nontarget plants. Do not apply directly except as specified on this label. Do not contaminate water when disposing of equipment washwaters."

Non-aquatic Uses:
"Drift or run-off may adversely affect nontarget plants. Do not apply directly to water or wetlands (swamps, bog, marshes, and potholes). Do not contaminate washwaters."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follow:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption3, the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

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3 If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and §152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement

exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium. 3.

You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. <u>You request that EPA amend your registration by deleting the uses for which the data are needed</u>. You are not required to submit data for uses which are no longer on your label.

6. <u>You request voluntary cancellation of the registration of your product(s) for which the data are needed</u>.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in

rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: MCPP Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR §152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158.120, Subpart C - Product Chemistry							
Product Identity and Composition							
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All		No	N/A	Yes[1]/	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	All		No	N/A	Yes[2]/	9 Months
Analysis and Certification of Product Ingredients							
62-1 - Preliminary Analysis of Product Samples	TGAI	All		No	N/A	Yes[3]/	12 Months
Physical and Chemical Characteristics							
63-2 - Color	TGAI	All		No	N/A	Yes[4]/	9 Months
63-3 - Physical State	TGAI	All		No	N/A	Yes[4]/	9 Months
63-4 - Odor	TGAI	All		No	N/A	Yes[4]/	9 Months
63-5 - Melting Point	TGAI	All		No	N/A	Yes[4,5]/	9 Months
63-6 - Boiling Point	TGAI	All		No	N/A	Yes[4,6]/	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All		No	N/A	Yes[4]/	9 Months
63-8 - Solubility	TGAI or PAI	All		No	N/A	Yes[4]/	9 Months

Table A

Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158 - Subpart C - Product Chemistry							
Physical and Chemical Characteristics (cont'd)							
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A		Yes[4]/	9 Months
63-10 - Dissociation Constant	TGAI or PAI	All	No	N/A		Yes[4]/	9 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No	N/A		Yes[4]/	9 Months
63-12 - pH	TGAI	All	No	N/A		Yes[4,7]/	9 Months
63-13 - Stability	TGAI	All	No	N/A		Yes[4]/	9 Months
Other Requirements							
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A		No	

Note: All = The total number of chemicals.

1/Complete information must be provided regarding the nature of the process (batch or continuous), relative amounts of beginning materials and the order in which they are added, chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

2/A detailed discussion must be submitted regarding all impurities, including nitrosamines, dibenzo-p-dioxins, and dibenzofurans that are or may be present at > 0.1 percent, based on knowledge of the beginning materials, intended and side chemical reactions in the manufacturing process, and any contamination during and after production.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data Chemical Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158 - Subpart C - Product Chemistry						

3/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity including "toxicologically significant" impurities such as dibenzo-p-dioxins and dibenzofurans for which certified limits are required. Complete, detailed descriptions of the analytical methods used must be submitted along with statements of their precision and accuracy. Reports of preliminary analyses should include for each sample the identity of each ingredient for which analysis was conducted, the quantity that was found, and the mean and relative standard deviation of reported analytical results. In addition, six samples must be analyzed for presence of nitrosamines by methods capable of detecting < 1 ppm nitrosamine: two samples must be analyzed shortly after production, two samples at 3 months after production, and two samples at 6 months after production.

4/Data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability) as required in 40 CFR Part 158 Subpart C and more fully described in the Pesticide Assessment Guidelines, Subdivision D. See Table B for addition requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.

5/Data on melting point are required if the technical chemical is a solid at room temperature.

6/Data on boiling point are required if the technical product is a liquid at room temperature.

7/Data on pH are required if the test substance can be diluted or dispersed in water.

Table A
Generic Data Requirements for MCPP[1] [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 - Environmental Fate							
Degradation Studies - Lab							
161-1 - Hydrolysis	PAIRA	B	1	Partially	00162656	Yes[2]	9 Months
		B,D	2	No	00162656	Yes[2]	9 Months
		B	3	No	00162656	Yes[2]	9 Months
		B,D,G	4	No	00162656	Yes[2]	9 Months
		B,D	5	No	00162656	Yes[2]	9 Months
Photodegradation							
161-2 - In Water	PAIRA	All	All	No	-	Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	All	All	No	-	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	-	-	No[3]	-	No[3]	
Metabolism Studies - Lab							
162-1 - Aerobic Soil	PAIRA	B	1	No	-	Yes	27 Months
		B	2	No	-		
		B	3	No	-		
		B,G	4	No	-		
		B	5	No	-		
162-2 - Anaerobic Soil	TGAI or PAIRA	-	-	No[3]	-	No[3]	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	2	No	-	Yes	27 Months
		D,G	4	No	-	Yes	27 Months
		D	5	No	-	Yes	27 Months

Table A

Generic Data Requirements for MCPP[1] [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 - Environmental Fate							
Metabolism Studies - Lab (cont'd)							
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	2	No	-	Yes	27 Months
		D	4	No	-	Yes	27 Months
		D	5	No	-	Yes	27 Months
Mobility Studies							
163-1 - Leaching and Adsorption/ Desorption	PAIRA	All	All	Partially	00160749 00162403 00162404	Yes[4]/ Yes[4]/ Yes[4]/	12 Months
163-2 - Volatility (Lab)	TEP	-	-	No	-	No[3]/	12 Months
163-2 - Volatility (Field)	TEP	-	-	No	-	No[3]/	12 Months
Dissipation Studies - Field							
164-1 - Soil	TEP	All	All	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	D	2	No	-	Yes	27 Months
		D	4	No	-	Yes	27 Months
		D	5	No	-	Yes	27 Months
164-3 - Forestry	TEP	G	4	No	-	Yes	27 Months
164-4 - Combination and Tank Mixes		-	-	-	-	No[5]/	
164-5 - Soil, Long-term	TEP	-		No	-	Reserved[6]/	

Table A

Generic Data Requirements for MCPP[1] [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 - Environmental Fate							
Accumulation Studies							
165-1 - Rotational Crops (Confined)	PAIRA	-		No	-	No[2]	
165-2 - Rotational Crops (Field)	TEP	-		No	-	No[2]	
165-3 - Irrigated Crops	TEP	D	2	No	-	Yes	39 Months
		D	4	No	-	Yes	39 Months
		D	5	No	-	Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	All	All	No	-	Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	D	2	No	-	Yes	12 Months
		D,G	4	No	-	Yes	12 Months
		D	5	No	-	Yes	12 Months

1/MCPP is formulated as an acid, salts, or ester. Data are required on each form as indicated by its individual use pattern (data requirements on MCPP-potassium salt will be fulfilled by data on MCPP acid because this inorganic salt is considered to be interconvertable with the MCPP acid form). Data on MCPP acid will be applicable to the organic salt and ester form only after data on the parent indicate that the chemical dissociates or degrades from the salt or ester form to the MCPP acid. Additionally, data on the organic salts or ester part of the formulation will be necessary to support registration. The rate and completeness of the dissociation or degradation reaction are essential to the development of the environmental fate profile of each registered MCPP chemical form. The process or processes and the rate at which this reaction occurs as well as any substantial side reactions are the target of the environmental fate data requirements.

2/The hydrolysis data requirement is only partially satisfied for the acid and potassium salt formulations; the requirement is not satisfied for the organic salt/ester forms of MCPP.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 - Environmental Fate (cont'd)							

3/This study is not required for the current use patterns.
4/The studies reviewed partially satisfy the adsorption/desorption data requirement for the unaged residues of MCPP only (acid and potassium salt formulations). Adsorption/desorption data are required for both the unaged and aged organic salt/ester forms of MCPP pesticides.
5/There are no current registered combination or tank mixes for MCPP pesticides.
6/The requirement for this study is reserved pending the results of the field dissipation study.

Table A

Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 - Toxicology							
Acute Testing							
81-1 - Acute Oral Toxicity - Rabbit	TGAI	B	1	Yes	00128266	No	
		B,D	2	Yes	00128266	No	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	B	1	Yes	00128265	No	
		B,D	2	Yes	00128265	No	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	All	All	No	-	Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	B	1	Yes	00128267	No	
		B,D	2	Yes	00128267	No	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	B	1	Yes	00128264	No	
	TGAI	B,D	2	Yes	00128264	No	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	All	All	No	-	Yes	9 Months

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 - Toxicology							
Acute Testing (cont'd)							
81-7 - Delayed Neurotoxicity - Hen	TGAI	All	All	No	-	No[1]/	
Subchronic Testing							
82-1 - 90-Day Feeding	TGAI						
- Rodent,		B	1	Yes	00158359	No	
		B,D	2	Yes	00158359	No	
		B	3	No	-	No[2]/	
		B,D,G	4	No	-	No[2]/	
		B,D	5	No	-	No[2]/	
- Nonrodent (Dog)	TGAI	All	All	No	-	No[2]/	
82-2 - 21-Day Dermal	TGAI	All	All	No	-	Yes	12 Months
82-3 - 90-Day Dermal	TGAI	All	All	No	-	No[2]/	
82-4 - 90-Day Inhalation	TGAI	All	All	No	-	No[2]/	
82-5 - 90-Day Neurotoxicity	TGAI	All	All	No	-	No[1]/	
Chronic Testing							
83-1 - Chronic Toxicity	TGAI						
- Rodent		All	All	No	-	No[2]/	
- Nonrodent (dog)		All	All	No	-	No[2]/	

Table A

Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 - Toxicology							
Chronic Testing (cont'd)							
83-2 - Oncogenicity	TGAI						
- Rat (preferred)		All	All	No	-	No[2]/	
- Mouse (preferred)		All	All	No	-	No[2]/	
83-3 - Teratogenicity	TGAI						
- Rat		B	1	Yes	00164569	No	
		B,D	2	Yes	00164569	No	
		B	3	No	-	Yes	15 Months
		B,D,G	4	No	-	Yes	15 Months
		B,D	5	No	-	Yes	15 Months
- Rabbit		B	1	Yes	00044282	No	
		B,D	2	Yes	00044282	No	
		B	3	No	-	Yes	15 Months
		B,D,G	4	No	-	Yes	15 Months
		B,D	5	No	-	Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	All	All	No	-	No[2]/	
Mutagenicity Testing							
84-2 - Gene Mutation Rat	TGAI	B	1	Yes	00123282	No	
		B,D	2	Yes	00123282	No	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 - Toxicology							
Mutagenicity Testing (cont'd)							
84-2 - Chromosomal Aberration	TGAI	B	1	No	-	Yes[3]/	12 Months
		B,D	2	No	-	Yes[3]/	12 Months
		B	3	No	-	Yes	12 Months
		B,D,G	4	No	-	Yes	12 Months
		B,D	5	No	-	Yes	12 Months
84-4 - Other Mechanisms Of Mutatenicity	TGAI	B	1	Yes	00158363	No	
		B,D	2	Yes	00158363	No	
		B	3	No	-	Yes	12 Months
		B,D,G	4	No	-	Yes	12 Months
		B,D	5	No	-	Yes	12 Months
SPECIAL TESTING							
85-1 - General Metabolism	PAI or PAIRA	All	All	No	-	No[2]/	
85-2 - Dermal Absorption	TGAI	All	All	No	-	Yes[4]/	12 Months

Note: Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range-finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.

1/MCPP, by virtue of its structure or known toxicity, does not require delayed neurotoxicity studies.

2/This study is not required for the registered use patterns.

3/A Chinese hamster bone marrow cytogenetics study is required on MCPP acid or MCPP potassium salt.

4/A dermal teratogenicity study in the rat may be needed if the results of the dermal absorption study indicate significant dermal absorption.

Table A
Generic Data Requirements for MCPP[1]/k[Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.390 - Reentry Protection							
132-1 - Foliar Dissipation	TEP	All	All	No	-	No[2]/	27 months
132-2 - Soil Dissipation	TEP	All	All	No	-	No[2]/	27 months
133-3 - Dermal Exposure	TEP	All	All	No	-	No[2]/	27 months
133-4 - Inhalation Exposure	TEP	All	All	No	-	No[3]/	
Sec. 158.75 - Requirements for Additional Data Applicator Exposure Monitoring							
Dermal Exposure, Outdoor	TEP	All	All	No	-	Yes[4]/	6 months
Respiratory Exposure, Outdoor	TEP	All	All	No	-	Yes[4]/	6 months
§158.440 - Spray Drift							
201-1 - Droplet Size Spectrum	TEP	All	All	No	-	No[5]/	
201-1 - Drift Field Evaluation	TEP	All	All	No	-	No[5]/	

1/See footnote 1 of §158.290, Environmental Fate.
2/Reentry data are required for commercial turf use. Data must reflect exposure resulting from harvesting and handling treated turf.
3/Reserved pending registrant submission and Agency evaluation of complete toxicology data base including dermal and inhalation toxicity.
4/Sites include commercial home lawns (hose end sprayer, power sprayer, back pack); and commercial turf (ground boom). Protocols are to be submitted in 6 months.
5/Spray drift data are not required under this Standard at this time because MCPP does not meet the human or phytotoxicity requirement under §158.142.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 - Wildlife and Aquatic Organisms							
Avian and Mammalian Testing							
171-1 - Acute Avian Oral Toxicity	TGAI	B	1	Yes	40116101	No	
		B,D	2	No[7/]	-	No[7/]	
		B	3	No	-	Yes	9 Month
		B,D,G	4	No	-	Yes	9 Month
		B,D	5	No	-	Yes	9 Month
171-2 - Avian Subacute Dietary Toxicity - Upland Game Bird	TGAI	B	1	Yes	40116101	No	
		B,D	2	No[7/]	-	No[7/]	
		B	3	No	-	Yes	9 Month
		B,D,G	4	No	-	Yes	9 Month
		B,D	5	No	-	Yes	9 Month
- Waterfowl		B	1	Yes	164095	No	
		B,D	2	No[7/]	-	No[7/]	
		B	3	No	-	Yes	9 Month
		B,D,G	4	Yes	28295	No	
		B,D	5	No	-	Yes	9 Month
171-3 - Wild Mammal Toxicity	TGAI	All	All	N/A[1/]	-	No	
171-4 - Avian Reproduction - Upland Game Bird and Waterfowl	TGAI	All	All	No		Reserved[2/]	
171-5 - Simulated and Actual Field Testing	TEP	B	1	No	-	Reserved[2/]	
		B,D	2	No[7/]	-	Reserved[4,7/]	
- Mammals and Birds		B	3	No	-	Reserved[4/]	
		B,D,G	4	No	-	Reserved[4/]	
		B,D	5	No	-	Reserved[4/]	

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 - Wildlife and Aquatic Organisms							
Aquatic Organism Testing							
172-1 - Freshwater Fish Toxicity							
- Coldwater Fish Species	TGAI	B	1	Yes	158366	No	
		B,D	2	No[7]	-	No[7]	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
- Coldwater Fish Species	TEP	B	1	No	-	No[3]	
		D	2	No	-	Yes	9 Months
		B	3	No	-	Reserved[4]	
		B,D,G	4	No	-	Yes	9 Months
		D	5	No	-	Yes	9 Months
- Warmwater Fish Species	TGAI	B	1	No	-	Yes	9 Months
		B,D	2	No[7]	-	No[7]	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months
- Warmwater Fish Species	TEP	B	1	No	-	Reserved[4]	
		D	2	No	-	Yes	9 Months
		B	3	No	-	Reserved[4]	
		D	4	No	-	Yes	9 Months
		D	5	No	-	Yes	9 Months
172-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	B	1	No	-	Yes	9 Months
		B,D	2	No[7]	-	No[7]	
		B	3	No	-	Yes	9 Months
		B,D,G	4	No	-	Yes	9 Months
		B,D	5	No	-	Yes	9 Months

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 - Wildlife and Aquatic Organisms							
172-2 - Acute Toxicity to Freshwater Invertebrates (cont'd)	TEP	B	1	No	-	Reserved[4]/	
		D	2	No	-	Yes	9 Months
		B	3	No	-	Reserved[4]/	
		D	4	No	-	Yes	9 Months
		D	5	No	-	Yes	9 Months
172-3 - Acute Toxicity to Estuarine and Marine Organisms - Fish, Mollusk, Shrimp	TGAI	All	All	No	-	Reserved[4]/	
	TEP	All	All	No	-	Reserved[4]/	
172-4 - Fish Early Life Stage, and Aquatic Invertebrate Life Cycle	TGAI	All	All	No	-	Reserved[4]/	
172-5 - Fish Life Cycle	TGAI	All	All	No	-	Reserved[5]/	
172-6 - Aquatic Organism Accumulation - Crustacean - Fish - Insect Nymph - Mollusk	TGAI	All	All	N/A[6]/	-	N/A[6]/	
172-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	All	All	No	-	Reserved[4]/	

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

§158.490 - Wildlife and Aquatic Organisms Footnotes

All = The total number of EPA registered uses or total number of chemicals depending on the column.
1/This study is currently not required.
2/Reserved pending receipt and evaluation of environmental fate studies.
3/Formulated product testing is not required because this pesticide has no aquatic uses and the maximum estimated environmental concentration is not greater than the lowest LC_{50}.
4/Reserved pending receipt and evaluation of acute toxicity and environmental fate studies.
5/Reserved pending receipt and evaluation of fish early life stage or invertebrate life cycle studies, if required.
6/See Environmental Assessment Chapter for data requirements.
7/Data for MCPP acid is sufficient for the potassium salt.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.540 - Plant Protection							
121-1 - TARGET AREA PHYTOTOXICITY	TEP	All	All	N/A	-	No	
NONTARGET AREA PHYTOTOXICITY							
TIER I							
122-1 - Seed Germination/ Seedling Emergence	TGAI	All	All	No	-	No	
122-1 - Vegetative Vigor	TGAI	All	All	No	-	No	
122-2 - Aquatic Plant Growth	TGAI	All	All	No	-	No	
TIER II							
123-1 - Seed Germination/ Seedling Emergence	TGAI	All	All	No	-	Yes	9 Months
123-1 - Vegetative Vigor	TGAI	All	All	No	-	Yes	9 Months
123-2 - Aquatic Plant Growth	TGAI	All	All	No	-	Yes	9 Months

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.540 - Plant Protection							
TIER III							
124-1 - Terrestrial Field Study	TEP	All	All	No	-	Reserved1/	
124-2 - Aquatic Field Study	TEP	All	All	No	-	Reserved1/	

All = The total number of use patterns or total number of chemicals, depending on the column.
1/Reserved pending receipt and evaluation of Tier II plant studies.

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.590 - Nontarget Insect							
NONTARGET INSECT TESTING - POLLINATORS							
141-1 - Honey Bee Acute Contact Toxicity	TGAI	B	2	No[4]	-	No[4]	
		B	3	No	-	Yes	9 Months
		B	4	No	-	Yes	9 Months
		B	5	No	-	Yes	9 Months
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	B	2	No[4]	-	No[4]	
		B	3	No	-	No[1]	
		B	4	No	-	No[1]	
		B	5	No	-	No[1]	
141-4 - Honey Bee Subacute Feeding Study	[Reserved][2]						
141-5 - Field Testing for Pollinators	TEP	B	2	No[4]	-	No[4]	
		B	3	No	-	No[1]	
		B	4	No	-	No[1]	
		B	5	No	-	No[1]	
NONTARGET INSECT TESTING - AQUATIC INSECTS							
142-1 - Acute Toxicity to Aquatic Insects	[Reserved][3]						
142-1 - Aquatic Insect Life Cycle Study	[Reserved][3]						
142-3 - Simulated or Actual Field Testing for Aquatic Insects	[Reserved][3]						

Table A
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Chemical	Does EPA Have Data Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.590 - Nontarget Insect							
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES Thru 143-3	[Reserved]3/						

1/Requirement deferred pending evaluation of data from the acute contact test.
2/Reserved pending development of test methdology.
3/Reserved pending Agency decision as to whether the data requirement should be established.
4/Data for MCPP acid is sufficient for the potassium salt.

Table B
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data for Chemical	Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158 - Subpart C - Product Chemistry							
Product Identity and Composition							
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No		N/A	Yes[1]/	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No		N/A	Yes[2]/	9 Months
61-3 - Discussion of Formation of Impurities	MP	All	No		N/A	Yes[3]/	9 Months
Analysis and Certification of Product Ingredients							
62-1 - Preliminary Analysis of Product Samples	MP	All	No		N/A	Yes[4]/	12 Months
62-2 - Certification of Ingredient Limits	MP	All	No		N/A	Yes[5]/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No		N/A	Yes[6]/	12 Months
Physical and Chemical Characteristics							
63-2 - Color	MP	All	No		N/A	Yes[7]/	9 Months
63-3 - Physical State	MP	All	No		N/A	Yes[7]/	9 Months

Table B
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data for Chemical Required?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
158 - Subpart C - Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-4 - Odor	MP	All	No	N/A	Yes[7]/	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes[7]/	9 Months
63-12 - pH	MP	All	No	N/A	Yes[7,8]/	9 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes[7]/	9 Months
63-15 - Flammability	MP	All	No	N/A	Yes[7,9]/	9 Months
63-16 - Explodability	MP	All	No	N/A	Yes[7,10]/	9 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes[7]/	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes[7]/	9 Months
63-19 - Miscibility	MP	All	No	N/A	Yes[7,12]/	9 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes[7]/	15 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No	

Table B
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

§158 - Subpart C - Product Chemistry Footnotes

Note: All = The total number of chemicals.

1/The product name, chemical name (Chemical Abstracts Index of Nomenclature or other well-defined name), nominal concentration, certified limits, Chemical Abstracts Service (CAS) Registry Number, and purpose of each active ingredient and each intentionally added inert must be provided for each manufacturing-use product. The name and upper certified limit must also be provided for each impurity or group of impurities for which a certified limit is required. The information on ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2/85).

2/Complete information must be provided regarding the nature of the process (batch or continuous), relative amounts of beginning materials and the order in which they are added, chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

3/A detailed discussion must be submitted for each manufacturing-use product regarding all impurities that are or may be present at > 0.1 percent, based on knowledge of the beginning materials, intended and side chemical reactions in the manufacturing process, and any contamination during and after production. A discussion regarding the possible presence of nitrosamines, dibenzo-p-dioxins, and dibenzofurans from any sources in the product are also required.

4/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certif required. Complete, detailed descriptions of the analytical methods used must be submitted along with statements of their precision and accuracy. Reports of preliminary analyses should include for each sample the identity of each ingredient for which analysis was conducted, the quantity that was found, and the mean and relative standard deviation of reported analytical results. In addition, six samples must be analyzed for presence of nitrosamines by methods capable of detecting < 1 ppm: two samples must be analyzed shortly after production, two samples at 3 months after production, and two samples at 6 months after production.

5/Upper and lower limits for each active ingredient and intentionally added inert ingredient, and upper limits for each impurity present at > 0.1 percent (w/w) and each additional "toxicologically significant" impurity such as dibenzo-p-dioxins and dibenzofurans that may be present at < 0.1 percent must be certified for each manufacturing-use product. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of the procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

6/For each manufacturing-use product, analytical methods must be provided to quantify each active ingredient and each "toxicologically significant" impurity. Each method must be accompanied by validation data indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

Table B
Generic Data Requirements for MCPP [Mecoprop] Acid (1) and its Potassium Salt (2), Diethanolamine Salt (3), Dimethylamine Salt (4), and Isooctyl Ester (5)

§158 - Subpart C - Product Chemistry Footnotes (cont'd)

7/Quantitative data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing/reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosive characteristics) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D. See Table A for additional requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.
8/Data on pH are required if the test substance can be diluted or dispersed in water.
9/Data are required on the flashpoint if the product is or contains a combustible liquid.
10/Data are required if the product contains any potentially explosive ingredients.
11/Data on viscosity are required if the product is a liquid.
12/Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING MCPP [Mecopropd] Acid or its Potassium Salt Diethanolamine Salt, Dimethylamine Salt and Isooctyl Ester

Data Requirement	Test Substance	Use Patterns	Chemical-	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission-
Sec. 158.340 Toxicology							
Acute Testing							
81-1 - Acute Oral - Rat	MP	All	All	No		Yes	9 Months
81-2 - Acute Dermal - Rabbit	MP	All	All	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	MP	All	All	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	MP	All	All	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	MP	All	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	All	No		Yes	9 Months

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . ," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the MCPP Standard

MRID Citation

00028295 Ross, D.B.; Burroughs, S.J.; Roberts, N.L. (1974) The Acute Toxicity (LC50:) of Mecoprop Technical (40% as Dimethylamine Salt Solution) to Mallard Duck. (Unpublished study received Jul 20, 1976 under 2217-624; prepared by Huntingdon Research Centre, submitted by PBI-Gordon Corp., Kansas City, Kans.; CDL:235458-B)

00044282 Irvine, L.F.H. (1980) Mecoprop Oral Teratogenicity Study in the Dutch Belted Rabbit: Report No. 1738R-277/5. (Unpublished study including submitter summary, received Aug 28, 1980 under 2217-EX-2; prepared by Hazleton Laboratories Europe, Ltd., England, submitted by PBI-Gordon Corp., Kansas City, Kans.; CDL:243169-A)

00123282 Carere, A.; Ortali, V.; Cardamone, G.; et al. (1978) Microbiological mutagenicity studies of pesticides in vitro. Mutation Research 57:277-286. (Also in unpublished submission received Dec 9, 1982 under 464-502; submitted by Dow Chemical U.S.A., Midland, MI; CDL:248984-B)

00128264 Wolfe, G.; Shults, S.; Killeen, J.; et al. (1982) Primary Dermal Irritation Study in Albino Rabbits with 2-(2-Methyl-4-chlorophenoxy)propionic Acid: Report Document No. 521-5TX-81-0165-002. (Unpublished study received May 2, 1983 under 39335-2; prepared in cooperation with Hazleton Laboratories America, Inc., submitted by Diamond Shamrock Agricultural Chemicals, Tuscaloosa, AL; CDL:250089-A)

00128265 Wolfe, G.; Shults, S.; Killeen, J.; et al. (1982) Acute Dermal Toxicity Study in Albino Rabbits with 2-(2-Methyl-4-chlorophenoxy) propionic Acid (MCPP): Report Document No. 521-5TX-81-0163-002. (Unpublished study received May 2, 1983 under 39335-2; prepared in cooperation with Hazleton Laboratories America, Inc., submitted by Diamond Shamrock Agricultural Chemicals, Tuscaloosa, AL; CDL:250089-B)

00128266 Wolfe, G.; Shults, S.; Killeen, J.; et al. (1982) Acute Oral Toxicity (LD50) Study in Rats with 2-(2-Methyl-4-chlorophenoxy)propionic Acid (MCPP): Report Document No. 521-5TX-81-0162-002. (Unpublished study received May 2, 1983 under 39335-2; prepared in cooperation with Hazleton Laboratories America, Inc., submitted by Diamond Shamrock Agricultural Chemicals, Tuscaloosa, AL; CDL: 250089-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the MCPP Standard

MRID Citation

00128267 Wolfe, G.; Shults, S.; Killeen, J.; et al. (1982) Primary Eye Irritation Study in Albino Rabbits with 2-(2-Methyl-4-chlorophenoxy) propionic Acid (MCPP): Report Document No. 521-5TX-81-0166-002. (Unpublished study received May 2, 1983 under 39335-2; prepared in cooperation with Hazleton Laboratories America, Inc., submitted by Diamond Shamrock Agricultural Chemicals, Tuscaloosa, AL; CDL:250089-D)

00158359 Kirsch, P. (1985) Report on the Study of the Toxicity of MCPP in Rats after 3 Months Administration in the Diet: Project No. 31S0047/8303. Unpublished study prepared by BASF Aktiengesellschaft. 376 p.

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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
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V. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

OMB Approval No.
2070-005
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No.
2070-005
Expires 11/30/8

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)